

Patent Application No. 09/469,399**Remarks**

The Office Action mailed November 21, 2002, has been received and reviewed. Claims 1 through 26 are currently pending in the application. Claims 1 through 26 are objected to in the Office Action, and claims 1 through 26 stand rejected. The Office Action also contains an objection to the specification due to certain informalities. Applicants, however, respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

Objection to the Specification

The specification of the present application is objected to for two informalities noted on page 2 of the Office Action. Applicants respectfully note that the amendments to the specification made herein correct such informalities and respectfully request that the objection to the specification be withdrawn.

Objection under 35 U.S.C. § 112

Claims 1 through 26 are objected to in the Office Action under the second paragraph of Section 112. In particular, it is asserted in the Office Action that the claims omit essential elements. However, Applicants note that claims 1 and 15 have been amended herein, and Applicants respectfully submit that claims 1 through 26 do not omit essential elements. Applicants, therefore, respectfully request that the objection to claims 1 through 26 under Section 112, second paragraph, be withdrawn.

35 U.S.C. § 103(a) Obviousness Rejections

Each of pending claims 1 through 26 stands rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over Wong et al. (U.S. Patent 5,534,263) in view of Conte et al. (U.S. Patent 5,780,057). A rejection under Section 103(a), however, is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. See, *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). In this case, Applicants respectfully submit that the combined teachings of Wong et al. and Conte et al. do not properly establish the *prima facie* obviousness of any of the pending claims. Therefore, Applicants respectfully request that the rejection of claims 1 through 26 under Section 103 be withdrawn.

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As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit that the combined teachings of Wong et al. and Conte et al. do not teach or suggest all the claim limitations of any one of claims 1 through 26. Applicants further submit that the combined teachings of Wong et al. and Conte et al. fail to provide the requisite motivation to combine and modify the teachings found within the cited references to arrive at the subject matter recited in the rejected claims. Consequently, Applicants respectfully submit that the combined teachings of Wong et al. and Conte et al. do not establish the *prima facie* obviousness of any one of claims 1 through 26.

I. The combined teachings of Wong et al. and Conte et al. do not teach or suggest each of the limitations of any of claims 1 through 14 or 18 through 26

Claims 1 through 14 and 18 through 26 are directed to various active agent dosage forms.

Amended claim 1 is an independent claim reciting:

[a]n active agent dosage form comprising; a first layer comprising an amount of swellable polymer sufficient to swell said first layer to a first length, said first length being sufficient to facilitate retention of said active agent dosage form within a stomach of a subject; a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to limit expansion of said second layer to a length less than said first length; at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.

Because they depend from claim 1, either directly or indirectly, each of claims 2 through 14 and 18 through 26 also incorporate each of the limitations recited in claim 1. Therefore, in order to establish the *prima facie* obviousness of claims 1 through 14 and 18 through 26, a reference or combination of references must at least teach or suggest each of the limitations recited in claim 1.

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Wong et al. does not teach or suggest a dosage form having each of the limitations recited in claim 1. Specifically, Applicants respectfully note that Wong et al. does not teach or suggest a dosage form having first and second layers. As a consequence, the teachings of Wong et al. do not even contemplate creation of a dosage form having a first layer or second layer characterized by the limitations recited in claim 1. Furthermore, the teachings of Wong et al. do not contemplate the use of one or more insoluble bands to bind multiple dosage form layers to ensure that such layers remain associated even as one expands to a greater extent than the other. Instead, the teachings of Wong et al. simply inform those of skill in the art that one or more insoluble bands may be provided around an erodible matrix containing an active agent to control or alter the rate at which the matrix erodes and the drug is released from the matrix. Considered alone, the teachings of Wong et al. do not establish the *prima facie* obviousness of claim 1.

It is asserted in the Office Action that combining the teachings of Wong et al. with the teachings of Conte et al. cures the shortcomings of Wong et al. and establishes the *prima facie* obviousness of the rejected claims. However, Conte et al. also fails to teach or suggest all the limitations that define the dosage form recited in claim 1. Conte et al. teaches a multi-layered dosage form that includes at least one layer formulated to swell to facilitate gastric retention as well as another layer formulated to deliver an active ingredient over time. However, the Conte et al. reference does not teach or suggest the use or provision of a band of insoluble material to bind the two or more layers included in the dosage form. In fact, Applicants respectfully submit that the teachings of Conte et al. would lead one of ordinary skill in the art away from a dosage form as recited in rejected claim 1. Therefore, Applicants further submit that the combined teachings of Wong et al. and Conte et al. cannot establish the *prima facie* obviousness of claim 1, and Applicants respectfully request that the rejection of claim 1 under Section 103 be withdrawn.

Applicants further request that the rejection of claims 2 through 14 and 18 through 26 under Section 103 be withdrawn. As already noted, each of these claims depends from claim 1 and incorporates each of the limitations recited in claim 1. Because the combined teachings of Wong et al. and Conte et al. do not teach or suggest each of the limitations recited in claim 1, the combination of references can not teach or suggest each of the limitations recited in any of claims 2 through 14 or claims 18 through 26. Thus, Applicants respectfully submit that the combined teachings of Wong et al. and Conte et al. do not establish the *prima facie* obviousness

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of any of claims 2 through 14 or claims 18 through 26, and Applicants respectfully request that the rejection of these claims under Section 103 be withdrawn.

II. The combined teachings of Wong et al. and Conte et al. do not teach or suggest each of the limitations of any of claims 15 through 17

Claims 15 through 17 recite methods of treating a subject with an active agent. Claim 15 is an independent claim reciting:

[a] method of treating a subject in need thereof with an active agent, the method comprising: administering to the subject a multilayered dosage form which is retained in a stomach of the subject over a prolonged period of time, the dosage form comprising: a first layer comprising an amount of swellable polymer, said amount being sufficient to swell said first layer such that said active agent dosage form is retained within the stomach of a subject; a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to swell to a lesser extent than the first layer; and at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.

Claims 16 and 17 depend from claim 15 and, as a result, also incorporate each of the limitations recited in claim 15. Thus, a combination of references can not establish the *prima facie* obviousness of any of claims 15 through 17, unless that combination teaches or suggests a method requiring the administration of a dosage form having all the limitations recited in claim 15.

Significantly, the method of claim 15 requires administration of a dosage form having limitations not taught or suggested by the combined teachings of Wong et al. and Conte et al. The dosage form administered in the method of claim 15 is characterized by the same limitations that define the dosage form of claim 1. As already discussed with regard to claim 1, the combined teachings of Wong et al. and Conte et al. do not teach or suggest a multi-layered dosage form having a first layer, a second layer, and at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, wherein the at least one band of insoluble binds the first layer and the second layer together. Therefore, Applicants respectfully submit that the combined teachings of Wong et al. and Conte et al. do not establish the *prima facie* obviousness of the rejected claims under Section 103, and Applicants respectfully request that the rejection of claims 15 through 17 under Section 103 be withdrawn.

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III. The combined teachings of Wong et al. and Conte et al. do not provide the suggestion or motivation required to establish *prima facie* obviousness

The combined teachings of Wong et al. and Conte et al. would not motivate one of ordinary skill in the art to modify the references or combine references' teachings in a way that would result in dosage forms or methods as recited in claims 1 through 26. Wong et al. does not teach or suggest a dosage form having multiple layers. Wong et al. teaches that insoluble bands may be positioned around erodible matrices to control or alter the release of active agents from such matrices, but because Wong et al. does not describe or suggest multi-layer dosage forms, wherein the multiple layers must be retained together during operation, the teachings of Wong et al. provide no suggestion regarding the utility of or benefits imparted by insoluble bands applied to multi-layered dosage forms. Therefore, applicants respectfully submit that, upon review of the teachings provided by Wong et al., one of ordinary skill in the art would find no motivation to modify the teachings of Wong et al. to arrive at the subject matter recited in any of the rejected claims.

Further, Applicants respectfully submit that the teachings of Conte et al. do not combine with the teachings of Wong et al. to provide the requisite suggestion or motivation to combine and modify the reference teachings to arrive at the subject matter recited in the rejected claims. The teachings of Conte et al. describe multilayer dosage forms having at least one layer formulated to swell to facilitate gastric retention as well as another layer formulated to deliver an active ingredient over time. Again, however, the teachings found in Conte et al. do not contemplate the use of one or more insoluble bands circumscribing and binding together the multiple layers included in the dosage form. On the contrary, the teachings of Conte et al. indicate that simple lamination of the multiple layers by compression is sufficient to provide a multilayer dosage form that will be retained intact within the stomach of a subject while delivering a desired active ingredient over time. *See, e.g., Conte et al.*, col. 4 – col. 5 and Examples 1 – 4. In that manner, the Conte et al. reference teaches away from a multi-layered dosage form designed for gastric retention, wherein the multiple layers are not only compression laminated but are also bound together using one or more insoluble bands. Upon review of the teachings and examples found in Conte et al., one of ordinary skill in the art would find banding of a multi-layered dosage form wholly unnecessary and would find no motivation to modify dosage form of Conte et al. to include one or more insoluble bands. Therefore, if presented the

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teachings of Wong et al. in combination with the teachings of Conte et al., one of ordinary skill in the art would have no motivation and would find no suggestion to modify the teachings of either reference to achieve the dosage forms and methods recited in claims 1 through 26.

Double Patenting

Claims 1 through 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 12 of U.S. Patent 6,120,803 to Wong et al. ("the '803 Patent") in view of Conte et al. However, such a rejection is appropriate only where the claims of a second patent are not patentably distinct over the claims of a first patent, which shares common ownership or inventorship. *See, M.P.E.P. § 804*. "A double patenting rejection of the obviousness type is 'analogous to a [failure to meet] the nonobviousness requirement of 35 U.S.C. 103,' except that the patent principally underlying the double patenting rejection is not considered prior art." *M.P.E.P. § 804* (citing *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967)). Therefore, the analysis employed in determining the propriety of an obviousness-type double patenting rejection should parallel the analysis used to determine the propriety of an obviousness rejection under Section 103.

In this instance, Applicants respectfully submit that the non-statutory double patenting rejection of claims 1 through 26 is improper. Specifically, Applicants submit that the subject matter recited in the pending claims is not rendered *prima facie* obviousness by the subject matter recited in claims 1 through 12 of the '803 patent when viewed in light of the teachings of Conte et al. Claims 1 through 12 of the '803 patent make no mention of multi-layer dosage forms, much less multi-layer dosage forms which include first and second layers characterized by the limitations recited in claim 1 and claim 15, the only independent claims pending in this case. Moreover, as has been explained in relation to the obviousness rejection under Section 103, the teachings of Conte et al. do not teach or suggest a multi-layer dosage form having first and second laminated layers, wherein the first and second layers are circumscribed by at least one band of insoluble material. Applicants respectfully submit that, when viewed in light of the teachings of Conte et al., the subject matter recited in claims 1 through 12 of the '803 Patent does not teach or suggest all of the limitations recited in any of pending claims 1 through 26. Applicants further submit that the combined teachings of the '803 Patent and Conte et al. do not provide one of ordinary skill in the art with the motivation necessary to combine and modify the

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teachings of the two references to arrive at the subject matter recited in the rejected claims. Therefore, Applicants submit that claims 1 through 26 pending in this case are patentably distinct from claims 1 through 12 of the '803 Patent, and Applicants respectfully request that the obviousness-type double patenting rejection of claims 1 through 26 be withdrawn.

CONCLUSION

Claims 1 through 26 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



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